

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
11 July 2002 (11.07.2002)

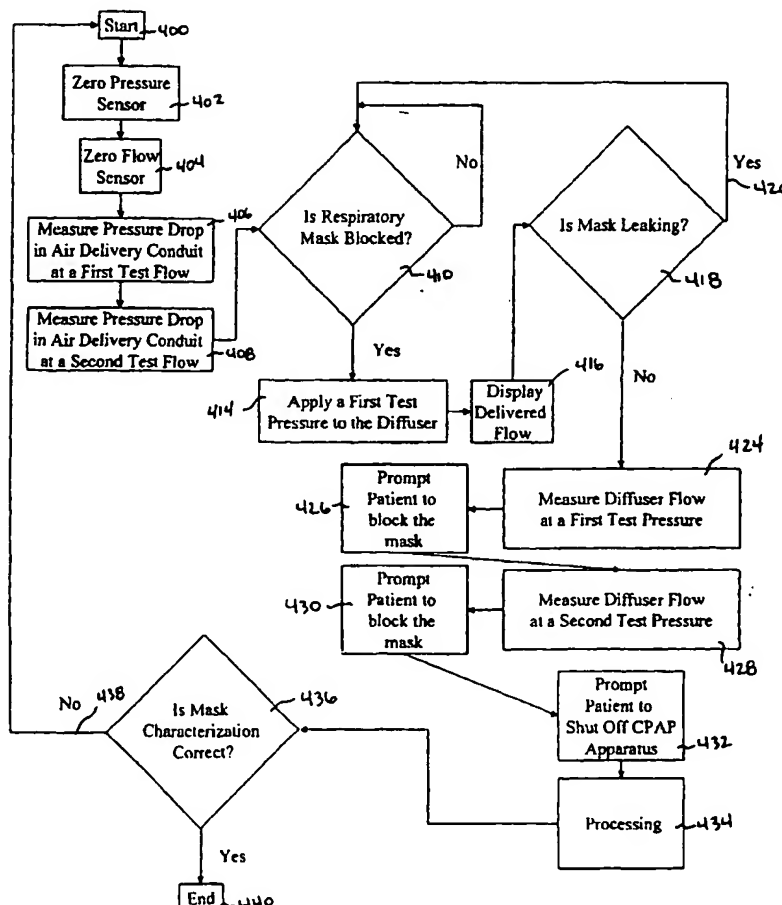
PCT

(10) International Publication Number
WO 02/053217 A1

- (51) International Patent Classification⁷: **A61M 16/00** (71) Applicant (for US only): **WICKHAM, Nicola, Frances** (executrix for the deceased inventor) [AU/AU]; 20 Hampden Road, Five Dock, New South Wales 2046 (AU).
- (21) International Application Number: **PCT/AU01/01673**
- (22) International Filing Date: **24 December 2001 (24.12.2001)** (72) Inventor: **WICKHAM, Peter, John** (deceased).
- (25) Filing Language: **English** (74) Agents: **DAVIDSON, Geoffrey, Robert** et al.; Halford & Co., Level 7, 1 Market Street, Sydney, New South Wales 2000 (AU).
- (26) Publication Language: **English** (81) Designated States (national): **AU, JP, US.**
- (30) Priority Data: **60/258,606 29 December 2000 (29.12.2000) US** (84) Designated States (regional): **European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).**
- (71) Applicant (for all designated States except US): **RESMED LTD.** [AU/AU]; 97 Waterloo Road, North Ryde, New South Wales 2113 (AU).
- Published:
— with international search report

[Continued on next page]

(54) Title: CHARACTERISATION OF MASK SYSTEMS



(57) Abstract: A method and a CPAP apparatus (10) for characterizing a plurality of different mask systems (14), e.g., masks and hoses, are provided. The CPAP apparatus (10) can be calibrated for different mask systems (14) and hoses (16) by including sensors (13,15) configured to measure flow and pressure at a flow generator (12) of the CPAP apparatus (10). When the flow generator (12) is fitted to a new mask system (14), or any changes are made to an existing mask system (14), mask or patient interface (34) and/or hose (16), a method of calibrating the flow generator (12) for the new mask system (14), mask (34) and/or hose (16) is provided. The method includes determining air flow characteristics of the hose (16) using flow measurements made during a first test period when the flow through the mask system (14) is open, measuring or estimating pressure in the mask system (14) during a second test period when the flow through the mask system (14) is blocked and determining air flow characteristics of the diffuser (36) of the mask system (14) using the air flow characteristics of the air delivery hose (16) determined during the first test period and the pressure measurements made during the second test period.

WO 02/053217 A1

WO 02/053217 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

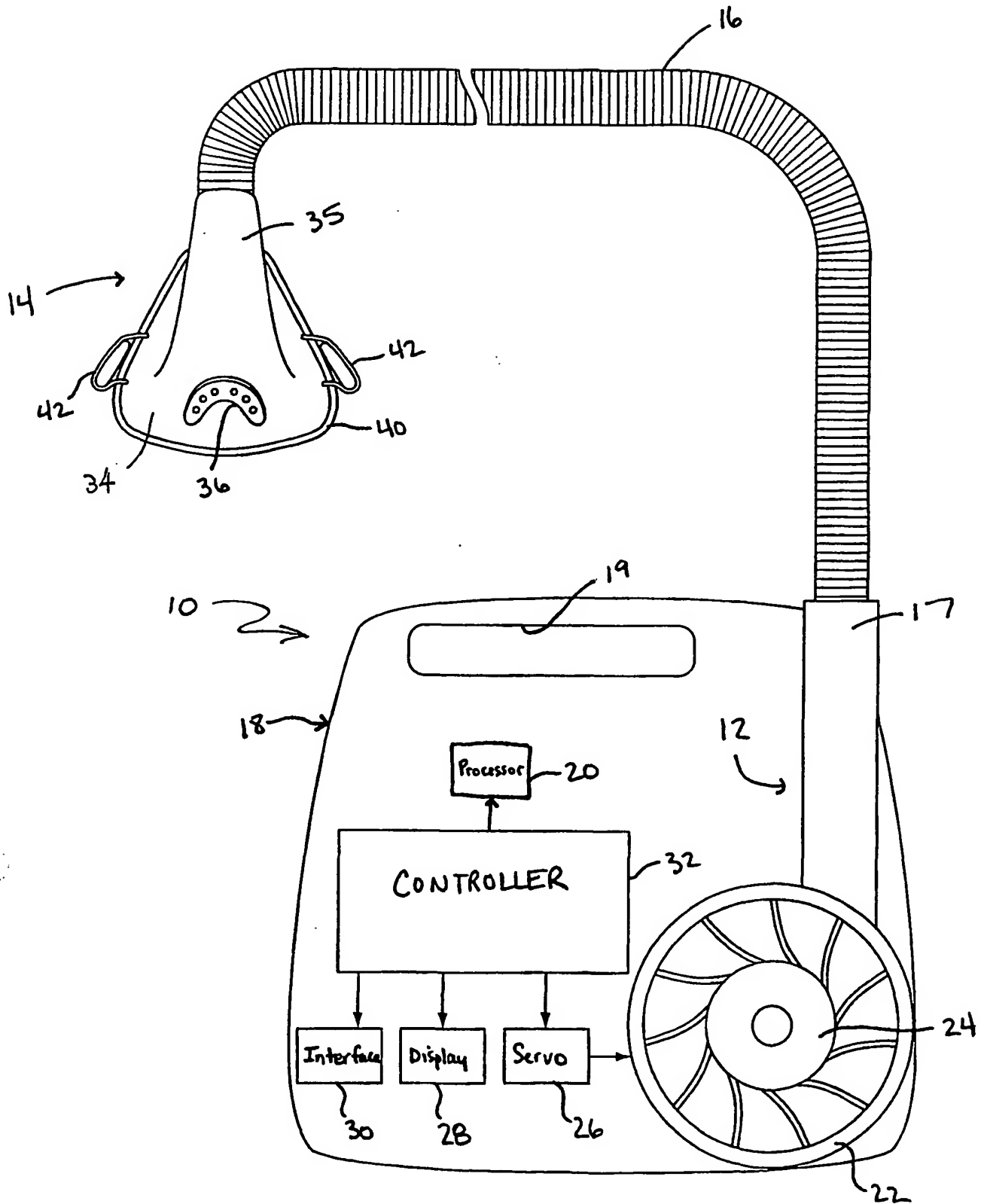


FIG. 1

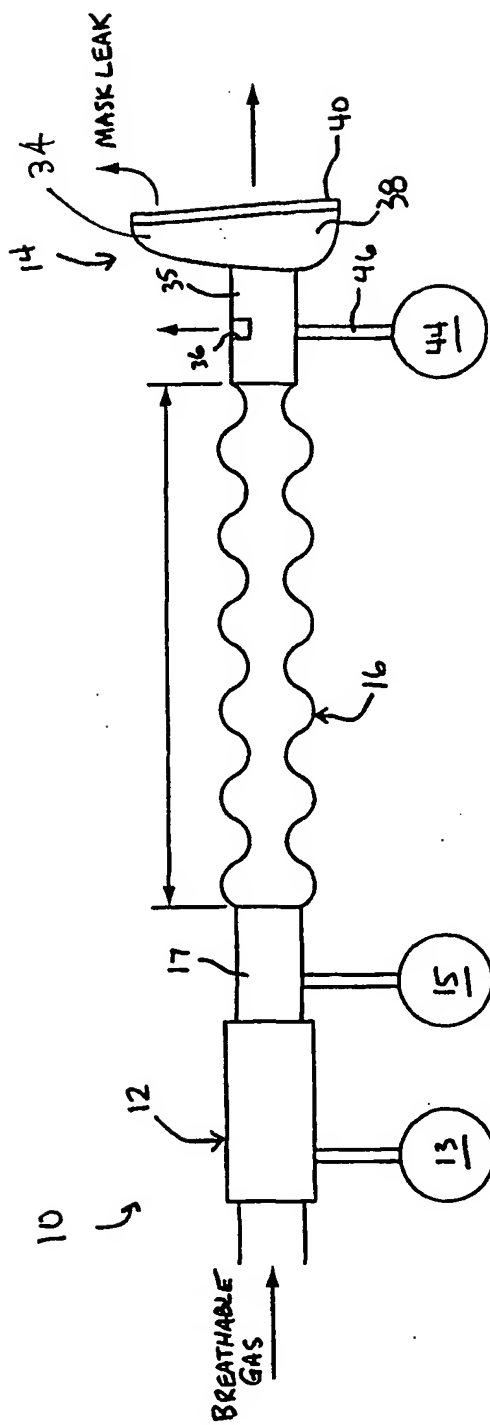


FIG. 2

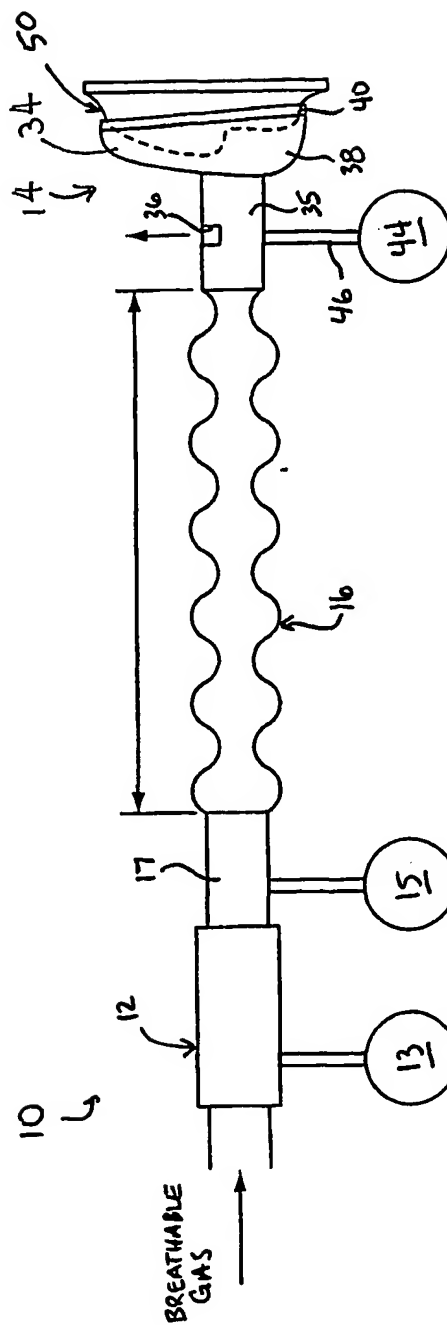


FIG. 3

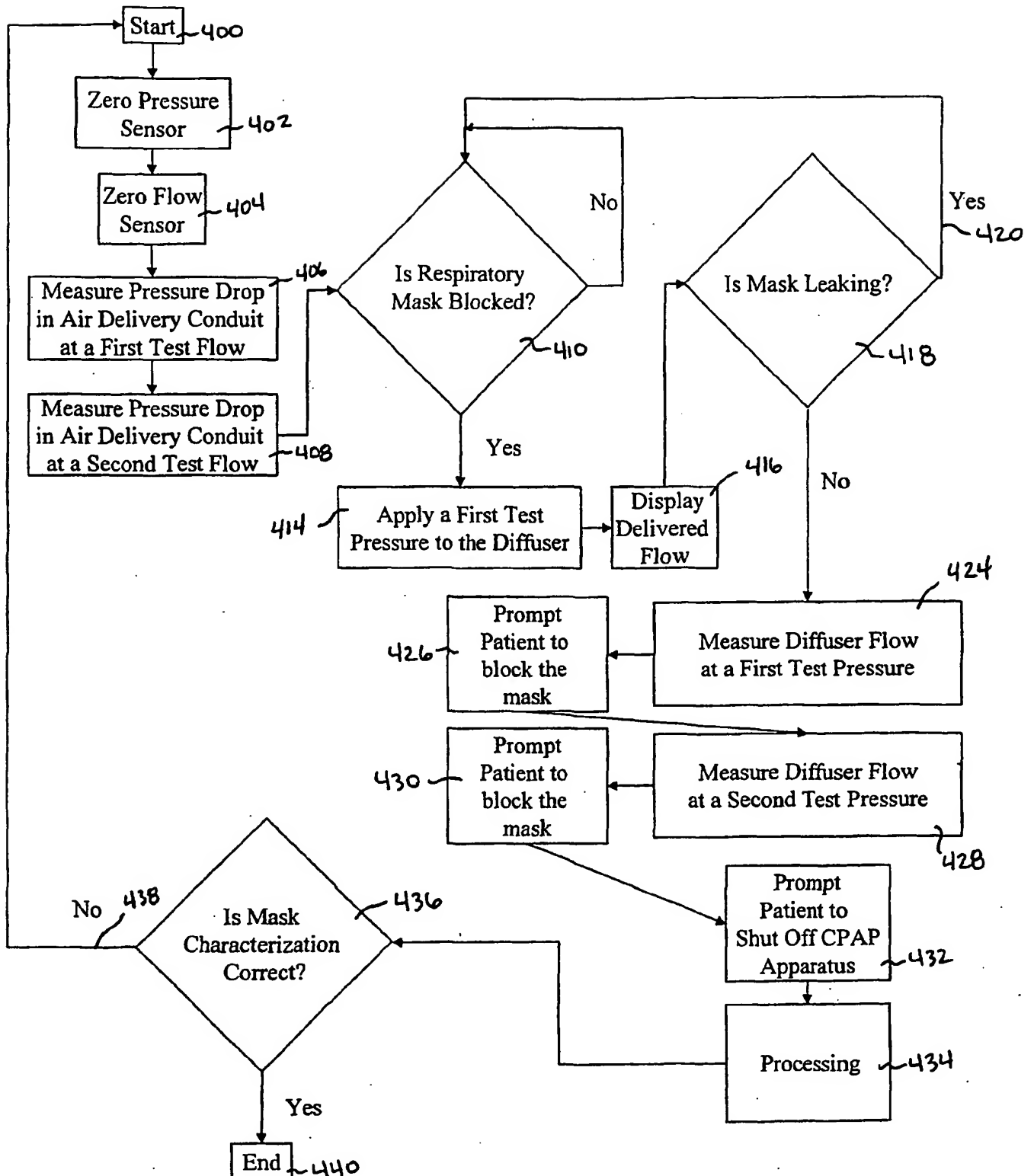


FIG. 4

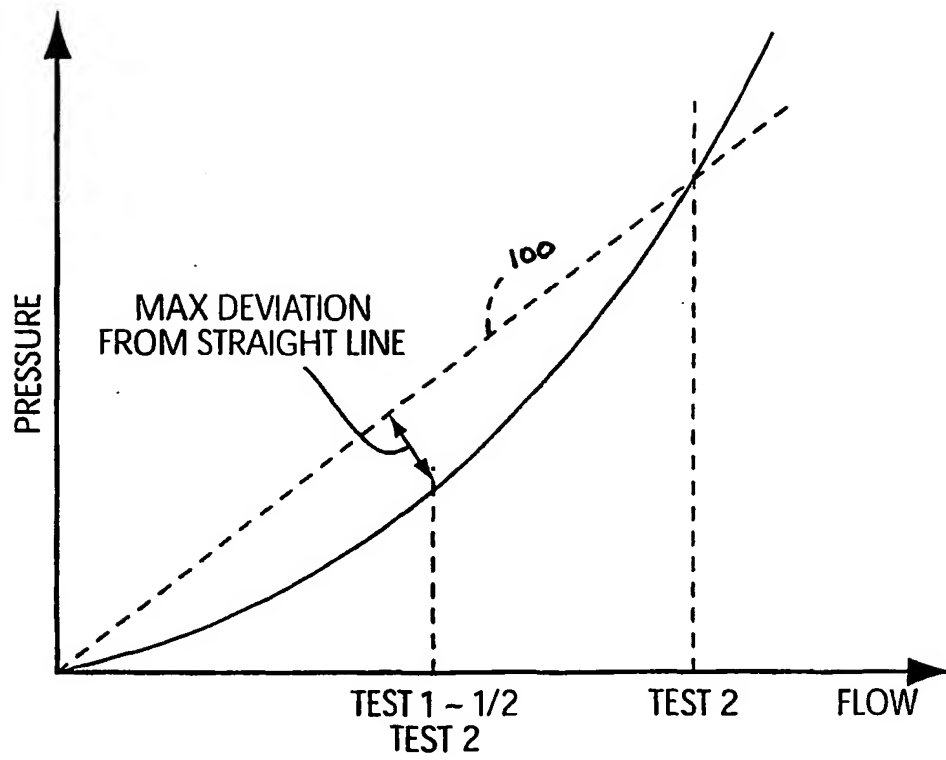


FIG. 5

CHARACTERISATION OF MASK SYSTEMS

This application claims priority from U.S. Provisional application serial number 60/258,606, filed on December 29, 2000, the contents of which are incorporated by reference in its entirety.

5

FIELD OF THE INVENTION

The invention generally relates to a method and an apparatus for characterizing mask systems used in treatment of sleep disordered breathing (SDB). More specifically, the invention relates to a method and apparatus for use with different mask systems that can determine air flow characteristics of the different mask systems.

10

BACKGROUND OF THE INVENTION

The use of nasal Continuous Positive Airway Pressure (CPAP) for the treatment of Obstructive Sleep Apnea (OSA) was taught by Sullivan and described in U.S. Patent 4,944,310, which is entitled "Device for Treating Snoring Sickness". The treatment generally provides a supply of air to a patient's upper airways at pressures, typically in the range of 4 to 20 cm H₂O, which acts to "splint" open the patient's airways. Typically, the CPAP apparatus includes (i) a blower for providing a source of pressurised breathable air to a patient, (ii) a patient interface to be removably worn by the patient, and (iii) an air delivery hose for transferring the pressurised breathable air from the blower to the patient interface. The blower typically includes an electric motor and impeller. One end of the air delivery hose or conduit is connected to the output of the blower and the other end is connected to the patient interface.

15

20

Some devices for treating SDB or assisting ventilation provide two pressure levels, one during patient inhalation and a different pressure during patient exhalation. The switching between two pressures may be triggered by a timer, a pressure sensor, a flow sensor, a volume sensor or some combination using techniques well known in the ventilator arts.

An automatically adjusting method and device was first described by Sullivan and Lynch in US Patent 5,245,995, which describes a pressure transducer that, in addition to detecting snoring sounds, can detect other respiratory parameters such as the rate of breathing, inhaled air flow volume and inhaled air flow rate. The device also included a feedback system controlling the output pressure of the air source so as to increase the output pressure in response to the detection of snoring or abnormal breathing patterns, and reduce the pressure in the absence of such patterns. The use of such a device can lead to improved patient comfort since patients receive lower pressures during the portion of their sleep when there are no indications of OSA, but higher pressures when they are needed. Examples of devices operating the this manner are the AutoSet® brand of nasal CPAP devices manufactured by ResMed Limited, Australia.

Other conditions may be treated by nasal ventilation such as Cheyne-Stokes breathing, as described in International Patent Application WO 99/61088. Such devices require very accurate measurement of flow and pressure.

OSA is an example of a broader class of disorders generally referred to as sleep disordered breathing (SDB). In this specification, a reference to apparatus for the treatment of OSA is intended to include a reference to apparatus for treating SDB.

Nasal CPAP apparatus for treating SDB form a special subgroup within the broader group of mechanical ventilators. Whilst mechanical ventilators are often closed systems with respect to airflow, the blower, conduit and patient interface system used for the treatment of sleep disordered breathing is typically an open system with respect to airflow. That is, the system for treating SDB typically includes a deliberate air leak. A deliberate leak is to be contrasted with unintentional leak. The patient interface in a system for treating SDB typically includes a diffuser which produces a deliberate air leak which, amongst other things, reduces rebreathing of exhaled air. In addition as in most systems, there exists the potential for unintentional leak flow. For example, if the mask is not correctly positioned on the face, or unsuitable for a particular face, there may be leak around the periphery of the face-contacting portion of the mask. In some applications of SDB treatment, for example to assist in correctly synchronizing the blower flow with spontaneous patient respiratory effort, it is important to measure accurately the leak, both deliberate and unintentional, from the system.

The "black box" which incorporates the blower, switches, power supply and control circuitry is sometimes termed a "flow generator". Alternatively, a source of high pressure air may be connected to a controllable valve arrangement to provide air at the required pressure and flow rates. All of these systems may be described as controllable sources of breathable gas.

In most modern devices for treating SDB, especially those providing sophisticated therapies, there is a need for the device to be able to measure accurately the pressure in the patient interface and the flow of air to the patient. One way this can be accomplished is to place flow and pressure sensors directly in the patient interface

(such as a mask). Another way this can be accomplished is to place the flow and pressure sensors in the flow generator and have a sense tube connected from the flow generator to the patient interface.

Whilst accurate measurements of, for example, pressure and flow can be made
5 directly at a mask, such an arrangement can be inconvenient from a patient's point of view since it may require additional sensing tubes to be carried from the flow generator to the patient interface. Sense tubes can be difficult to assemble, difficult to clean and may become tangled during use. Alternatively, if the characteristics of the conduit and patient interface are known, it is possible to estimate the desired variables,
10 such as pressure and flow, in the mask using measurements in the flow generator.

Hence there is a need for a way to measure the characteristics of the conduit and patient interface. In this way, the sophisticated apparatus for treating SDB can measure accurately the mask pressure without requiring sense tubes to be connected between the flow generator and the mask.

15 A large variety of mask systems are today available and each has different characteristics, such as different pressure drop along the conduit and diffuser flow. Furthermore, the characteristics of different samples of a given mask system can vary due to variation during manufacturing. In order that a given flow generator be able to work with a range of mask systems, each mask system must be characterized by the
20 manufacturer for use with the flow generator and the characteristics may be stored in the flow generator, for example, or in some other recordable medium device. In the event that new mask systems are developed, the flow generator may need to be returned to the manufacturer to be tested with the new mask system.

The flow generator then generates a flow and pressure model of this particular hose and mask system and uses these parameters to calculate hose pressure drop, diffuser flow and mask leak as part of its normal operation. The procedure is prompted on the LCD display with checks to make sure the operator is doing the right thing. The characterization procedure takes less than 1 minute.

There is a need for a method and apparatus which enables the characteristics of a wide range of patient interfaces and conduits to be determined without requiring that a flow generator be returned to the manufacturer.

10 SUMMARY OF THE INVENTION

One aspect of the invention is to overcome the short comings of the prior art. Another aspect is to provide a breathing assistance apparatus, e.g., a CPAP apparatus, that can be used with a variety of mask systems having different pressure and/or flow characteristics.

(1) 15 According to one preferred embodiment of the present invention, there is provided a method for determining air flow characteristics of a mask system connected to CPAP apparatus comprising a flow generator, the mask system including an air delivery hose and a patient interface including a diffuser, the flow generator including a controllable air blower, a flow sensor and a pressure sensor. The method 20 includes determining air flow characteristics of the air delivery hose using flow measurements made during a first test period when the flow through the patient interface is open; measuring pressure in the patient interface during a second test period when the flow through the patient interface is blocked; and determining air flow characteristics of the diffuser using the air flow characteristics of the air delivery

hose determined during the first test period and the pressure measurements made during the second test period.

2) In accordance with an embodiment of the invention, the mask system is characterised to determine the pressure drop along the conduit as a function of blower
5 flow rate. In accordance with an embodiment of the invention, the pressure drop across the diffuser is determined as a function of mask pressure.

(2) According to another embodiment of the invention, a method is provided for determining air flow characteristics of an air delivery hose connected to a flow generator in a CPAP apparatus, the flow generator including a controllable air blower,
10 a flow sensor and a pressure sensor. The method comprises measuring an air flow rate through the controllable air blower during a test period; and determining air flow characteristics of the air delivery hose using the flow rate measurements made during the test period.

According to another embodiment, a method is provided for determining air
15 flow characteristics of a mask system connected to a controllable source of breathable gas, the mask system including an air delivery hose and a patient interface. The method comprises measuring an air flow rate at the controllable source of breathable
gas during a controlled pressure test period when the mask system is open; measuring
a pressure at the controllable source of breathable gas during a controlled flow test
20 period when the mask system is blocked; and determining air flow characteristics of the mask system based on the measured pressure and the measured air flow rate made during the controlled pressure test period and the controlled flow test period, respectively.

(9)

In still another embodiment, a CPAP apparatus useful in treatment of a patient includes a housing; a respiratory mask system in communication with the housing, the respiratory mask system comprising an air delivery hose and a patient interface including a diffuser; a flow generator configured to deliver a supply of breathable gas to the patient and being associated with the housing, the flow generator being

5 controllable to supply a controllable source of breathable gas to the patient interface through the air delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period; and a processor configured to determine a plurality of air flow characteristics

10 of the respiratory mask system at least based on the plurality of flow measurements made during the test period.

Another embodiment encompasses a machine readable medium containing machine executable instructions for carrying out the method according to any one of claims 1-16.

17, 15 In still another embodiment, a CPAP apparatus useful in treatment of a patient, the CPAP apparatus comprises a housing; a respiratory mask system in communication with the housing, the respiratory mask system comprising an air delivery hose and a patient interface including a diffuser orifice; a flow generator configured to deliver a supply of breathable gas to the patient and being associated

20 with the housing, the flow generator being controllable to supply a controllable source of breathable gas to the patient interface through the air delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period; means for determining air flow characteristics of the air delivery hose using flow measurements made during a first

portion of the test period when the flow through the patient interface is open; means for measuring pressure in the patient interface during a second portion of the test period when the flow through the patient interface is blocked; and means for determining air flow characteristics of the orifice using the air flow characteristics of the air delivery hose determined during the first portion of the test period and the pressure measurements made during a second portion of the test period.

(8) In yet another embodiment, a CPAP apparatus for use with a respiratory mask system comprising an air delivery hose and a patient interface including a diffuser, comprises a housing; a flow generator configured to deliver a supply of breathable gas to the patient and being associated with the housing, the flow generator being controllable to supply a controllable source of breathable gas to the patient interface through the air delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period; and a processor configured to determine a plurality of air flow characteristics of the respiratory mask system at least based on the plurality of flow measurements made during the test period. A respiratory mask system for use with this CPAP apparatus is also envisioned.

(3) Also, a method is provided for calibrating a flow generator in a CPAP apparatus for use with a mask system including a diffuser and an air delivery hose connecting the flow generator and the mask system. The method comprises providing the flow generator with two different air flows, representative of a pressure drop in the air delivery hose when flow through the mask system is open; providing the mask system with two different pressures, representative of a flow of the diffuser and other

leaks out of the mask system; and blocking flow through the mask system while providing the mask system with the two different pressures.

1001

In accordance with an embodiment of the invention, in apparatus including a blower and a conduit, with the conduit connected to the blower outlet, a flow sensor

5 for measuring the flow of air at the blower outlet and a pressure sensor for measuring the air pressure at the blower outlet, there is provided a method for estimating the pressure drop along the conduit for a range of blower flow rates by modelling the pressure drop along the conduit as a quadratic function of flow with two parameters, and determining the two parameters by conducting two tests: (i) a first test in which

10 the blower is operated at a first flow rate and develops a first blower outlet pressure; and (ii) a second test in which the blower is operated at a second flow rate and develops a second blower outlet pressure.

(11)

In accordance with an embodiment of the invention, in apparatus including a blower and a conduit, with the conduit connected to the blower outlet, a flow sensor

15 for measuring the flow of air at the blower outlet, a pressure sensor for measuring the air pressure at the blower outlet, and a mask including a diffuser, the diffuser having a diffuser flow, there is provided a method for estimating the pressure drop across the diffuser for a range of blower flow rates by modelling the pressure drop across the diffuser as a quadratic function of mask pressure and blower flow. Although certain

20 embodiments of the invention are illustrated and described herein as having certain features, one skilled in the art would recognize that alternative embodiments of the invention could be provided based on at least one or more features, either individually or in combination, of the illustrated and described embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The benefits of the present invention will be readily appreciated and understood from consideration of the following detailed description of embodiments of this invention, when taken with the accompanying drawings, wherein:

5 Fig. 1 is a illustrative diagram showing a CPAP apparatus in accordance with the principles of the present invention;

 Fig. 2 is a schematic diagram of the CPAP apparatus shown in Fig. 1, wherein air flow to the patient is open;

 Fig. 3 is a schematic diagram of the CPAP apparatus shown in Fig. 1, wherein
10 air flow to the patient is blocked;

 Fig. 4 is an illustrative diagram showing a method in accordance with the principles of the present invention; and

 Fig. 5 is an illustrative diagram showing pressure plotted versus flow for the CPAP apparatus shown in Fig. 1.

15

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1 - 3 show a CPAP apparatus for treating a patient in accordance with the principles of the present invention. In the illustrated embodiment, the CPAP apparatus, generally indicated at 10, comprises a controllable air blower or flow
20 generator 12 that is in communication with a respiratory mask system, generally indicated at 14. The respiratory mask system 14 includes an air delivery hose 16 that connects the respiratory mask system 14 to the flow generator 12 to supply breathable gas through the respiratory mask system 14 to the patient.

The flow generator 12 is configured to deliver a supply of breathable gas to the patient at a specific flow rate and pressure, for example. As shown in Figures 2 and 3, the flow generator 12 includes a flow sensor 13 and a pressure sensor 15, to measure flow rate and pressure respectively, at an output 17 of the flow generator 12. The output 17 is preferably connected to the air delivery hose 16.

The flow generator 12 is configured to supply a controllable source of breathable gas, such as oxygen, to the mask system 14 through the air delivery hose 16 during a test period, which will be described in greater detail below. A plurality of flow measurements, for example, flow rate and pressure, of the controllable source of breathable gas are made during the test period at the output 17 of the flow generator 12.

The flow generator 12 is capable of delivering the source of breathable gas at a flow up to about 100 L/min, for example, at low pressures, ranging from about 0.25 to about 2 cm H₂O, smoothly and accurately.

As best shown in Fig. 1, the flow generator 12 can be provided within the housing 18, which can be made from a sufficiently resilient material, such as plastic or metal. Alternatively, the flow generator 12 can be provided remote from the housing 18.

The housing 18 may include an opening or slot 19 formed in the exterior thereof, which may be used as a handle to transport the CPAP apparatus 10. The resilient structure of the housing 18 can substantially helps support and protect a processor 20, an impeller 22, a motor 24, a servo-control circuit 26, a display 28, a user interface 30 and a controller 32. The controller 32 may be configured to control the operation of one or more of the processor 20, the impeller 22, the motor 24, the

servo-control circuit 26, the display 28, and the user interface 30, as is generally known.

As seen in Fig. 1, the user interface 30 and the display 28 are provided in the housing 18 of the CPAP apparatus 10 and are configured to control and manipulate various functions that may be available to the particular CPAP apparatus 10. The user interface 30 may be in the form of a barcode, a keyboard, a mouse, a touch screen, a remote terminal or a voice activation system, for example, to accept input from a user, such as a patient or doctor, for example. The display 28 may be a touch screen display or an LCD display and may be configured to display various parameters, such as, for example, air flow characteristics of the air delivery hose 16 or mask system 14, the flow rate measured by the flow sensor 13 and the pressure measured by the pressure sensor 15. The display 28 can be configured to display delivered flow (by the flow generator 12) with a prompt so that a user or patient can minimize delivered flow before making air flow characteristic measurements.

The motor 24 is coupled to the impeller 22 to drive the impeller 22. When driven, the impeller 22 generates a source of breathable gas, which can be supplied through the air delivery hose 16 to the mask system 14.

The processor 20 is configured and arranged to determine a plurality of air flow characteristics of the respiratory mask system 14 using a plurality of flow measurements made during the test period. These air flow characteristics could be displayed on the display 28, for example.

Additionally, the processor 20 may be capable of performing various calculations to a specific accuracy, for example, 32 bit floating point. The processor

20 may be configured and arranged to perform calculations at any other accuracy as well, which could depend on the desired calculation and application, for example.

The servo-control circuit 26 cooperates with the processor 20 and the flow generator 12 to allow for the maintenance of a pressure in the mask system 14, for example, within strictly defined error limits.

Table 1, as shown below, models a preferred minimum accuracy and a preferred optimal accuracy for various system parameters, such as delivered flow accuracy, stability and linearity and delivered pressure accuracy and stability.

Parameter	Minimum Accuracy	Optimal Accuracy
Delivered flow accuracy	+/- 3L/min (same as mask leak requirement)	+/- 1.5 L/min ($\frac{1}{2}$ mask leak requirement)
Delivered flow stability	Same as mask leak requirement over any period of use	$\frac{1}{2}$ mask leak requirement over any period of use
Delivered flow linearity	<5% deviation from straight line (Fig. 5)	<2% deviation from straight line (Fig. 5)
Delivered pressure accuracy	+/- 0.5 cmH ₂ O at 20 cmH ₂ O	+/- 0.25 cmH ₂ O at 20 cmH ₂ O
Delivered pressure stability	+/- 0.5 cmH ₂ O over any period of use	+/- 0.25 cmH ₂ O over any period of use

Table 1

As shown in Figs. 1-3, the air delivery hose 16 may be any conventional hose. However, in some applications, such as in some hospital and clinical situations with acute or sick patients, different requirements may be needed for the hose system 16. In particular it is likely that an antibacterial filter with ongoing maintenance would be beneficial in those situations.

In this situation, an abbreviated calibration of the hose, which will be described in greater detail below, may be done automatically or manually every time

the mask is disconnected from the patient. This system could also track use of antibacterial filters and warn when they are getting clogged and need to be changed.

The mask system 14 is connected to an air supply source provided by the flow generator 12 by the air delivery hose 16. The mask system 14 may be integrally
5 attached to the air delivery hose 16 or may be connected thereto with fasteners, such as clamps, for replacement or interchangeability of the mask system 14.

The air supply source may deliver unregulated air to the mask system 14, because the pressure sensor 15 associated with the flow generator 12 may be configured to
determine the required pressure of the air needed by the patient by the relative strength
10 of the patient's breaths.

The mask system 14 includes a patient interface or mask 34 and an elongated projecting portion 35, which may be connected to the air delivery hose 16. A diffuser 36, in the form of an orifice, is formed in the elongated projecting portion 35 and
diffuses air exhaled by the patient. Other masks may be used with apparatus
15 according to an embodiment of the invention. For example, apparatus in accordance with the invention may be used to determine the flow characteristics of a mask system such as the MIRAGE™ mask, the ULTRA MIRAGE™ mask, the BUBBLE™ mask or the MODULAR™ mask, all of which are manufactured by ResMed Limited, Australia.

20 The patient interface 34 may be any one of a number of different patient interfaces, such as a nasal mask, a nose and mouth mask, a full-face mask, nasal prongs (or cannulae) and nasal pillows. Generally, the patient interface 34 includes some form of mask retaining feature, such as headgear, to position the mask system 14 on the patient's face and to counterbalance the force which results from the

application of pressurized air which seeks to push the mask 34 or mask system 14 off the patient's face.

The diffuser 36 can be passive or semi-active, e.g., the diffuser 36 could be an opening, a plurality of openings, or an opening or openings that are partially covered,
5 grated etc., that allow air to pass through. .

The mask 34 is shown as a nasal mask and has a generally triangularly-shaped chamber 38 constructed from a relatively rigid material, such as polycarbonate, with an open side which, when in use, is positioned against the patient's face. The edge of the open side, i.e., a face-contacting portion 40, helps form a seal on the patient's face.
10 The face-contacting portion 40 is typically soft to assist with patient comfort and may be made from foam, rubber or polystyrene, for example.

A good seal should be provided between the patient's face and the face-contacting portion 40, with few leaks because leaks can cause air jetting and noise, which may be uncomfortable for the patient. Thus, mask 34 includes a number of
15 headgear-receiving portions 42 extending from opposite sides thereof to receive straps or other portions of the headgear, for example. Patient comfort is important and should be considered when selecting the type of mask 34 since the patient may be sleeping or resting while wearing the mask 34.

In accordance with one embodiment of the invention, the pressure in the
20 patient interface can be estimated once the conduit characteristics have been determined. In such an embodiment it is only necessary to determine the pressure at the blower outlet and the flow at the blower outlet in order to estimate the pressure in the patient interface, in conjunction with known conduit characteristics. Hence such an embodiment does not require a pressure transducer in the patient interface, or to be

connected to the patient interface via a sense tube. Furthermore, such an embodiment of the invention can be used in conjunction with a wide variety of commercially available masks which do not include pressure transducers in the mask, or pressure sense tubes in the mask.

5 The pressure delivered to the entrance of the patient's airways can also be measured directly in the patient interface 34. In this case, a pressure sensor 44, for example, a pressure transducer, may be mounted on or near the patient interface 34 and in communication with the interior chamber 38 or the projecting portion 35 of the mask 34 by way of a port or linking sensing tube 46. Alternatively, a sensing tube can
10 be connected between an appropriate port on the patient interface 34 and a pressure sensor (not shown) located remotely from the patient interface 34, such as in the air blower housing 18.

 In an alternative embodiment, although not shown, the CPAP apparatus can include an under or over pressure alarm coupled to a pressure tube extending from the
15 mask 34 for accurate measurements of mask pressure. This configuration may generally be best suited to provide variable pressure regimes. The under or over pressure alarm can measure pressure at the flow generator 12 to allow the maintenance of a continuous accurate model of the hose pressure drop and so allows the alarm system to measure pressure at the flow generator 12.

20 Characteristics for common masks and hose systems could be stored in the flow generator or a removable storage medium. Alternatively, those common characteristics could be manually entered via keyboard or barcode. Thus, the CPAP apparatus 10 may include a slot, for example, that is configured to allow a removable storage medium to be inserted into the slot for storing collected data or characteristics

for common masks and hose systems. The slot could be conveniently located anywhere on the CPAP apparatus, but should be located so minimal effort is required to insert and remove the storage medium from the CPAP apparatus 10.

The removable storage medium could be a magnetic or flash type of storage, which is commonly compatible with personal computers, handheld devices, cameras, and printers and is capable of storing hundreds of megabytes of data at a minimum.

Additionally, the removable storage medium could contain information about the mask system 14 or may include other parameters provided by a physician, for example. In this case the removable storage medium would have read from and write to capabilities and information that was imparted to the removable storage medium by the patient or the physician could be utilized by the CPAP apparatus 10 to control certain parameters. For example, different masks have different flow characteristics, it would be beneficial to impart information about the mask onto the removable storage medium so the CPAP apparatus could vary the provided air pressures or flow rates accordingly. In this case, it would be inexpensive for the patient to change masks because the mask information and characteristics could easily be changed to accommodate different masks, for example. Data for each particular mask can be provided by the mask manufacturer and when the patient purchases the mask, he or she could simply insert the card into the CPAP apparatus 10 and the apparatus could reconfigure itself accordingly.

In the CPAP apparatus 10, the flow generator 12 may be preset to operate within a given speed range giving coarse control of the pressure which is delivered to the patient through the air delivery hose 16. However, the actual pressure at the patient interface will vary throughout the respiratory cycle. For instance, as the

patient or other user inhales, the pressure measured at the patient interface increases while during exhalation the measured pressure decreases. The average air flow to the patient is assumed to be zero, as the air supplied to the patient is effectively balanced by air exhaled by the patient.

5 The pressure delivered to the entrance of the patient's airways can be estimated by measuring the pressure at the output 17 of the flow generator 12 and applying a correction factor in accordance with the known characteristics of the relevant conduit and patient interface, as will be described in greater detail below.

10 In most mask systems, there exists the potential for leak flow. For example, if the mask is not correctly positioned on the face, or unsuitable for a particular face, there may be leak around the periphery of the face-contacting portion of the mask. In some applications, it is important to measure accurately the leak from the system, for example in a spontaneously breathing patient, to assist in correctly synchronizing the air flow from the flow generator 12 with patient respiratory effort.

15 The accuracy of the flow and pressure measurements, as shown in Table 1, has a direct effect on the accuracy of a derived mask leak. However this accuracy will not effect the accuracy of a zero point of mask leak. Any zero drift in the measurements will effect both the scale and zero of mask leak.

20 A model showing the mask components (e.g., hose pressure drop, mask diffuser flow, and any other leaks) as quadratic expressions of pressure drop in regard to flow can be represented by the following quadratic expression:

$$\text{Pressure Drop} = A * \text{Flow} + B * \text{Flow}^2$$

The term A is attributed to friction losses, which are proportional to flow, and the term B is based on the Bernoulli equation where pressure drop is proportional to flow squared (Flow^2).

To obtain a more accurate measurement of mask leak, a flow blocking member 50 (Fig. 3) can be provided to block portions of the patient interface 34 and the projecting portion 35 so that flow through the mask system 14 is blocked. To ensure a proper fit, a shape of the flow blocking member 50 is complementary to a shape of the patient interface 34. Also, the shape of the flow blocking member 50 may be representative of a human nose, a human face or a partial human face. The flow blocking member 50 may be shaped such that it can serve to block flow in a number of masks having different configurations. The flow blocking member 50 may be affixed to the flow generator 12 so that it does not become lost and remains easily accessible to the patient, or the flow blocking member 50 can be free from attachment to the flow generator 12.

Reference will now be made to Fig. 4, in which a method for characterizing different mask systems in accordance with the principles of the invention. The method can model various characteristics of mask components, such as pressure drop in the hose 16, mask diffuser 36 flow and any other leaks in the mask system 14.

In Fig. 4, a flow chart is used to represent the method for characterizing different mask systems according to the principles of the present invention. At 400, the method begins. At 402, the pressure sensor 15 associated with the flow generator 12 is zeroed, and at 404, the flow sensor 13 associated with the flow generator 12 is zeroed. During data collection, the delivered flow, as measured by the flow sensor 13,

and the delivered pressure, as measured by the pressure sensor 15, should be kept as constant as possible.

At 406, a pressure drop in the air delivery hose 16 is measured at a first test flow rate. At 408, a pressure drop in the air delivery hose 16 is measured at a second test flow rate. The quadratic expression having constants Hose A and Hose B can be used to determine or calculate air flow characteristics of the air delivery hose 16. The quadratic expressions are represented as follows:

$$\text{Hose } A = (yX^2 - xY^2) / (xX^2 - Xx^2) \text{ and}$$

$$\text{Hose } B = (xY - yX) / (xX^2 - x^2X)$$

10

The pressure drops in the air delivery hose 16 at the first and second flow rates are represented as y and Y, respectively. Leaks in the diffuser 36 at a lower flow rate and at a higher flow rate are represented as x and X, respectively. It should be noted that the positive quadratic nature of the typical pressure/flow characteristic of these components, the first and second flow rates (or pressures) provide substantially better resolution with one at a high value and the other at half of the high value. This relationship is shown in Fig. 5, wherein test 1 is a flow rate having half the value of test 2, which is a flow rate having a high value. In Fig. 5, a maximum linear deviation from the straight line 100 (about 5%) is shown corresponding to flow rate represented by test 1, which is the value equal to half of the high value.

20

The mask calibration procedure produces the following measurements, as shown in Table 2, which are analyzed to produce the A and B coefficients for the mask system model described above:

Name	Parameter	Example value
HoseTF1	Lower test flow for hose	40 L/min
HoseTP1	Pressure drop down hose at lower test flow	0.1 to 0.4 cmH ₂ O
HoseTF2	Upper test flow for hose	80 to 100 L/min
HoseTP2	Pressure drop down hose at upper test flow	1 to 4 cmH ₂ O
DiffTP1	Lower diffuser test pressure	6 cmH ₂ O
DiffTF1	Flow at lower diffuser test pressure	10 to 20 L/min
DiffTP2	Upper diffuser test pressure	12 cmH ₂ O
DiffTF2	Flow at upper diffuser test pressure	15 to 40 L/min

Table 2

The values shown in Table 2 are examples only and are not limiting, rather they are provided for understanding only.

- 5 The true test pressures (TrueDiffTP1, TrueDiffTP2) for the diffuser can be calculated using HoseA and HoseB using the following equations:

$$\text{TrueDiffTP1} = \text{DiffTP1} - \text{Hose A} * \text{HoseTF1} - \text{Hose B} * \text{HoseATF1}^2$$

and

$$\text{TrueDiffTP2} = \text{DiffTP2} - \text{Hose A} * \text{HoseTF2} - \text{Hose B} * \text{HoseATF2}^2,$$

- 10 where DiffTP1 is the diffuser flow at a lower pressure for the diffuser and where DiffTP2 is the diffuser flow at a higher pressure for the diffuser.

In this way, the mask pressure can be estimated from known hose characteristics without requiring a pressure transducer in the mask, or directly connected to the mask.

- 15 At 410, the apparatus 10 prompts a user for a determination on whether the mask 34 or mask 14 is blocked or not. If the respiratory mask 34 is open, as denoted by 412, the apparatus 10 continues to prompt the user until the user blocks the mask 34, for example, with the flow blocking member 50. If the mask 34 is blocked, as

denoted by 414, a first test pressure is applied to the diffuser 36. The mask 34 can be blocked for example, by positioning the flow blocking member 50 adjacent a patient interface of the mask 34, for example.

At 416, the first test pressure, or delivered air flow, is displayed on a display of
 5 the CPAP apparatus 10. At 418, the CPAP apparatus prompts a user to determine whether the mask system 14 is leaking. If so, at 420, control proceeds back to 410. If not, control proceeds to 424, at which the flow of the diffuser 36 at a first test pressure is measured and after which, at 426, the CPAP apparatus prompts (actually reminds) the patient or user to keep the mask blocked with the flow blocking member 50. At
 10 428, measurements of diffuser flow of the diffuser 36 at a second test pressure (usually a lower pressure than the first test pressure, but not necessarily lower) and after which, at 430, the CPAP apparatus prompts (actually reminds) the patient or user to keep the mask 34 blocked with the flow blocking member 50. After measuring the diffuser flow at the first and second pressures, the user is prompted to shut off the
 15 CPAP apparatus at 432. At 434, processing begins.

During processing, with a processor, for example, the quadratic expression having constants Diff A and Diff B can be used to determine or calculate air flow characteristics of the mask 34. The quadratic expressions are represented as follows:

$$\text{Diff } A = \frac{(zV^2 - vZ^2)}{(vV^2 - Vv^2)} \text{ and}$$

$$\text{Diff } B = \frac{(vZ - zV)}{(vV^2 - v^2V)},$$

wherein v is a lower pressure for the diffuser 36, V is an upper pressure for the diffuser, z is a true lower pressure for the diffuser 36 and Z is a true upper pressure for the diffuser 36.

In an alternative embodiment, the background level of the flow generator 12 can be measured to characterize background noise during testing of the diffuser. The background level can be subtracted from a raw snore signal to derive a true snore level on the CPAP apparatus 10 and other flow generators that measure snore. This procedure could be used to calibrate the snore scale factor in the case where the flow blocking member 50 includes some type of snore source to perform in this manner.

In accordance with the measurements shown in Fig. 5, the test pressure or flow is held substantially constant for about 10 to about 20 seconds with mean flows and pressures being recorded during this time period.

During this operation, the mask system 14 is pressurized at the highest test pressure to expose any leaks. This can be checked by observing the displayed flow on the display, for example, and adjusting the flow blocking member 50 so that the displayed flow remains substantially constant and at a minimum.

During the operation and implementation of the above described method, there are a number of consistency checks that can be done at 436 to check whether the characterization of the mask is correct. If characterization is correct, then the method ends. If the characterization is not correct for some reason, the method starts over, at 400, but if the characterization is correct, then the method ends at 440.

Described below is one hypothetical example to further illustrate the principles of the method described in Fig. 4. The results of which are shown in Table 3.

For a test flow of 40L/min, for example, a pressure drop = $\text{HoseA} * F + \text{HoseB} * F^2 = 0.75 \text{ cm H}_2\text{O}$. If a hypothetical mask system has a diffuser leak that has a flow of 50 L/min at a mask pressure of 20 cm H₂O, and that 10 cmH₂O of this is the

linear component, the two diffuser constants would be $\text{DiffA} = 0.2$ and $\text{DiffB} = 4 \times 10^{-3}$.

³. At a test flow of 20 L/min, the test pressure (at the mask) will be 5.6 cm H₂O.

To calculate the hose pressure drop for the diffuser test flows, the following formula is used: $\text{HoseDrop} = \text{HoseA} \cdot F + \text{HoseB} \cdot F^2$. At a flow of 20 L/min, the hose pressure drop = 0.3125 cm H₂O and the diffuser test pressure (at the flow generator) = 5.9125 cm H₂O. At a flow of 50 L/min, however, the hose pressure drop = 1.01562 cm H₂O and the diffuser test pressure (at the flow generator) = 21.01562 cm H₂O.

Table 3, as shown below, summarizes the results for our example.

Parameter	Test value	Result	Test Value
Hose test flow 1	40 L/min	Test pressure for this	0.75 cmH ₂ O
Hose test flow 2	80 L/min	Test pressure for this	2 cmH ₂ O
Diffuser test pressure 1	5.9125 cmH ₂ O	Diffuser flow at this pressure	20 L/min
Diffuser test pressure 2	21.0125 cmH ₂ O	Diffuser flow at this pressure	50 L/min
Derived results:			
Hose A	HoseB	DiffA	DiffB
0.0125	1.5625×10^{-4}	0.2	4×10^{-3}

Table 3

10 The square law non linearity in the pressure and flow sensors described above will have a minimal effect on this system, as these are added to the square law characteristics of the mask system, and so will tend to be automatically calibrated into the method described in Fig. 4. Further, errors in the zero point of the flow and pressure sensors are accounted for during the method described in Fig. 4.

15 The functions shown and described above in accordance with the principles of the invention can be executed in any type of programming language. An example of fragments of generic source code is shown in the attached APPENDIX. The fragments of generic source code are shown in a generic computing language, such as, for example, C++, but may be implemented in other generic programming languages or programs as well.

20

In another form of the invention, apparatus is provided including a blower or flow generator, the blower including a pressure and flow sensor, the apparatus including a display for prompting a user and a mask blocking tool. The apparatus is programmed to perform the series of steps shown in Table 4. Table 4 shows what the flow generator does during each step, what the user is prompted to do and how the user should respond to the prompt. In the first step, the system is zeroed. Steps 2 and 3 constitute the part of the sequence where the hose characteristics are measured. In steps 4 and 5, the user is prompted to block the mask and the blocking is subsequently verified. In steps 6 and 7 the diffuser characteristics are measured whilst the mask is blocked. Finally in steps 8 and 9, the data collected during the previous steps is processed to determine the conduit characteristics and the diffuser characteristics. Also, in step 9, the data and results are checked for consistency.

Step	Flow Generator does	Prompt	User response
1	Zero of pressure and flow sensors	Ensure that mask is connected to flow generator and not patient	Set up mask system as required Press key when ready
2	Measure hose pressure drop at test flow 1 (~40 L/min)	Measuring hose characteristics	Wait
3	Measure hose pressure drop at test flow 2 (~80 L/min)	Measuring hose characteristics	Wait
4	Ask operator to block mask	Block mask with the mask blocking tool	Press key when done
5	Test for properly blocked mask: Apply diffuser test pressure 2 (~12 cmH ₂ O) and display delivered flow	Check that the mask is not leaking and that display flow is minimum	Press key when done
6	Measure diffuser at test pressure 2 (~12 cmH ₂ O)	Testing diffuser, Hold mask blocked	Wait
7	Measure diffuser at test pressure 1 (~6 cmH ₂ O)	Testing diffuser, Hold mask blocked	Wait
8	Turn off flow generator	Finished, remove mask from blocking tool	Remove tool and wait
9	Do mask characterisation and check for consistency	Report any errors	Accept characterisation or return to step 1

Table 4

5 Notes:

1. For all measurements, the test pressure or flow should be held steady for 10 to 20 seconds with mean flows and pressures recorded during this time.
2. The measured pressures during steps 2 and 3 can be very low (0.2 to 2 cmH₂O). This may entail accurate and steady control of the fan at unusually low (for CPAP) pressures. The ideal mode of control is constant flow delivery.
3. In step 5, a good leak proof seal is provided using the blocking tool. During this step, the mask is pressurised at the highest test pressure to expose any leaks. This can be checked by observing the displayed flow and adjusting the blocking tool so this is steady and minimum.
4. There are a number of consistency checks that can be done in step 8 to check the characterisation. Some of these are:

- Check on bounds of the test pressures and flow.

- Check on expected values for the A and B factors for the hose drop and diffuser leak models.
- Check that none of the A and B factors are negative (the pressure flow curves must have an increasing gradient).

5

The foregoing presentation of the described embodiments is provided to enable any person skilled in the art to make or use the present invention. Various modifications to these embodiments are possible, and the generic principles presented herein may be applied to other embodiments as well. For example, the invention may be implemented in part or in whole as analog or digital circuitry, as a hard-wired circuit, as a circuit configuration fabricated into an application-specific integrated circuit, or as a firmware program loaded into non-volatile storage or a software program loaded from or into a data storage medium as machine-readable code, such code being instructions executable by an array of logic elements such as a microprocessor or other digital signal processing unit.

In another example, apparatus and methods in accordance with the invention may use predetermined characteristics of the conduit in order to determine the characteristics of the diffuser. In this way, instead of a characterisation procedure using two steps namely a first part in which the mask is not blocked and a second part in which the mask is blocked, a characterisation procedure may only require the second step, the first step already having been done at an earlier stage. Hence if a technician or physician were to carry out one complete characterisation, that is both conduit and mask diffuser, and then at a later stage only change the mask and diffuser, it would not be necessary to recharacterise the conduit. Alternatively, if the apparatus were to be used with a conduit whose character was already known and stored in the

apparatus (for example, having been determined in a factory test), only the second step of the procedure would be necessary.

Thus, the present invention is not intended to be limited to the embodiments shown above but rather is to be accorded the widest scope consistent with the

5 principles and novel features disclosed in any fashion herein.

APPENDIX

Code fragment for mask characterization:

```

5  /* -- Function to calculate a and b coefficients for hose and
   Diffuser ----
       see LB P46. Mode = 'd' for debug prints

       Has some primitive error checking
10      Global Inputs:

           double HoseTf1, HoseTf2;      Hose Test flows in L/min (HoseTf1 ~ 40
           L/min, HoseTf2 ~ 80L/min)
15      double HoseTp1, HoseTp2;      Hose test pressures in cmH2O (HoseTp1 >
           HoseTp2)

           double DiffTp1, DiffTp2;      Diffuser test pressures in cmH2O
           (DiffTp1 ~ 6cm, DiffTp2 ~ 12 cmH2O)
20      double DiffTf1, DiffTf2;      Diffuser Test flows in L/min.

           Global Outputs:

           double Hosea, Hoseb;          Hose a and b coefficients
25      double Diffa, Diffb;          Diffuser a and b coefficients
           */

           char Doab(char mode)
           {
30      double dtp1, dtp2;              // diffuser real test pressures (minus
           hose drop)
           double x, y, X, Y;          // Temp inputs for clarity
           int i;
35      // ----- Do hose drop -----
           -----

           x= HoseTf1;
           y= HoseTp1;
40      X= HoseTf2;
           Y= HoseTp2;

           if(x>X || y>Y) {
           if(mode=='d') cprintf("\r\nError in Hose test params: x= %f, X=%f,
45      y=%f, Y=%f",x,X,y,Y);
           return('e');
           }

           Hosea=(y*X*X-Y*x*x)/(x*X*X-X*x*x);      // the a coefft
           Hoseb=(x*Y-y*X)/(X*X*X-x*x*X);          // The b coefft

```

```

// ----- Do real diffuser test pressures (remove effect of hose
drop) ---

dtp1=DiffTp1-(DiffTf1*Hosea+Hoseb*DiffTf1*DiffTf1);
5      // Must use diffuser test flows!

dtp2=DiffTp2-(DiffTf2*Hosea+Hoseb*DiffTf2*DiffTf2);

10  if(mode=='d') cprintf("\r\n Diffuser test pressures dtp1= %f, dtp2=
%f",dtp1, dtp2);

// ----- Do diffuser -----
-----

15  x= DiffTf1;
    y= dtp1;
    X= DiffTf2;
    Y= dtp2;

20  if(x>X||y>Y){
    if(mode=='d') cprintf("\r\nError in Diffuser test params: x= %f,
X=%f, y=%f, Y=%f",x,X,y,Y);
    return('E');
    }

25  Diffa=(y*X*X-Y*x*x)/(x*X*X-X*x*x); // the a coefft

    Diffb=(x*Y-y*X)/(X*X*x-x*x*X); // The b coefft

30  if(Diffa<0.0){
    if(mode=='d') cprintf("\r\nError in diffuser measurements, Diffa -
ve %6.4f",Diffa);
    return('D');
    }

35  return(' ');

    }

40

```

Code fragment for mask pressure and leak calculation:

```

/* ----- Function to calculate mask pressure and leak -----
-----
5  Uses calculated hose and diffuser a and b's and input flow and
   pressure
   if(mode=='d') debug printout

   Has some primitive error checking
10  returns 'e' on errors

   Global inputs:

15  double Hosea, Hoseb, Diffa, Diffb; Hose and mask A & B coefficients

   Global Outputs:

   double Maskpress, MaskLeak;          Mask pressure (cmH2O) and leak
20  (L/min)

   */

char Domaskleak(char mode, double FGpress, double FGflow)
25
   // FGpress= Pressure at flow generator (cmH2O)
   // FGflow = Air flow from flow generator (L/min)
   {

30  double Diffflow, tosqr;

   if(Hosea==0||Diffa==0){
       if(mode=='d') cprintf("\r\n Error, A&B's not set !");
       return('e');
35  }

   Maskpress=FGpress-(Hosea*FGflow+Hoseb*FGflow*FGflow); // calculate
   real mask pressure

40  tosqr=Diffa*Diffa+4.0*Diffb*Maskpress;
   // this bit to avoid -ve square roots (could be better)
   if(tosqr<0.000001) tosqr=0.000001;

45  Diffflow=(sqrt(tosqr)-Diffa)/(2.0*Diffb); // do diffuser flow

   if(mode=='d') cprintf("\r\n Diffuser flow= %5.3f",Diffflow);

   Maskleak=FGflow-Diffflow;

50  return(' ');

```

CLAIMS:

1. A method of determining air flow characteristics of a mask system connected to CPAP apparatus comprising a flow generator, the mask system including an air delivery hose and a patient interface including a diffuser, the flow generator
5 including a controllable air blower, a flow sensor and a pressure sensor, the method comprising:

determining air flow characteristics of the air delivery hose using flow measurements made during a first test period when the flow through the patient interface is open;

- 10 measuring pressure in the patient interface during a second test period when the flow through the patient interface is blocked; and

determining air flow characteristics of the diffuser using the air flow characteristics of the air delivery hose determined during the first test period and the pressure measurements made during the second test period.

15

2. A method according to claim 1, further comprising processing the air flow characteristics of the air delivery hose and the air flow characteristics of the diffuser.

20

3. A method according to any one of claims 1 or 2, wherein the determining of the air flow characteristics of the air delivery hose is calculated as a function of a quadratic expression with two hose constants.

4. A method according to claim 3, wherein the two hose constants comprise:

$$\text{Hose } A = \frac{(yX^2 - xY^2)}{(xX^2 - Xx^2)} \text{ and}$$

$$\text{Hose } B = \frac{(xY - yX)}{(xX^2 - x^2X)},$$

5 wherein x is a lower air flow for the air delivery hose, X is an upper air flow for the air delivery hose, y is a pressure drop in the air delivery hose at the lower air flow and Y is a pressure drop in the air delivery hose at the upper air flow.

5. A method according to claim 4, wherein the two hose constants (Hose A, Hose B) are used to calculate a true lower test pressure (TrueDiffTP1) and a true upper test pressure (TrueDiffTP2) for the diffuser,

wherein the true lower test pressure is defined as $\text{TrueDiffTP1} = \text{DiffTP1} - \text{HoseA} * x - \text{HoseB} * \text{HoseA}(x)^2$, where DiffTP1 is the diffuser flow at a lower pressure for the diffuser, and

15 wherein the true higher test pressure is defined as $\text{TrueDiffTP2} = \text{DiffTP2} - \text{HoseA} * X - \text{HoseB} * \text{HoseA}(X)^2$, where DiffTP2 is the diffuser flow at a higher pressure for the diffuser.

6. A method according to any one of claims 1-5, wherein the determining of the air flow characteristics of the mask system is calculated as a function of a quadratic expression with two diffuser constants (Diff A, Diff B).

7. A method according to claim 6, wherein the two diffuser constants comprise:

$$\text{Diff } A = \frac{(zV^2 - vZ^2)}{(vV^2 - Vv^2)} \text{ and}$$

$$\text{Diff } B = \frac{(vZ - zV)}{(vV^2 - v^2V)},$$

5 wherein v is a lower pressure for the diffuser, V is an upper pressure for the diffuser, z is a true lower pressure for the diffuser and Z is a true upper pressure for the diffuser.

8. A method according to any one of claims 1-7, further comprising
10 blocking the patient interface with a flow blocking member having a shape that is complementary to a shape of the patient interface.

9. A method according to claim 8, wherein the shape of the flow blocking
member is representative of at least one of a human nose and a human face.
15

10. A method according to any one of claims 8-9, further comprising
affixing the flow blocking member to the patient interface.

11. A method of determining air flow characteristics of an air delivery hose
20 connected to a flow generator in a CPAP apparatus, the flow generator including a controllable air blower, a flow sensor and a pressure sensor, the method comprising:
measuring an air flow rate through the controllable air blower during a test period; and

determining air flow characteristics of the air delivery hose using the flow rate measurements made during the test period.

12. A method of determining air flow characteristics of a mask system
5 connected to a controllable source of breathable gas, the mask system including an air delivery hose and a patient interface, the method comprising:
- measuring an air flow rate at the controllable source of breathable gas during a controlled pressure test period when the mask system is open;
- measuring a pressure at the controllable source of breathable gas during a
10 controlled flow test period when the mask system is blocked; and
- determining air flow characteristics of the mask system based on the measured pressure and the measured air flow rate made during the controlled pressure test period and the controlled flow test period, respectively.

13. A method in accordance with claim 12, further comprising controlling
15 the source of breathable gas to deliver air at a first substantially constant pressure and subsequently at a second substantially constant pressure during the controlled pressure test period.

14. A method in accordance with claim 13, wherein the first substantially
20 constant pressure is lower than the second substantially constant pressure.

15. A method in accordance with any one of claims 12-14, further comprising controlling the source of breathable gas to deliver air at a first

substantially constant flow rate and subsequently at a second substantially constant flow rate during the controlled flow test period.

16. A method in accordance with claim 15, wherein the first substantially
5 constant flow rate is lower than the second substantially constant flow rate.

17. A CPAP apparatus useful in treatment of a patient, the CPAP apparatus comprising:

a housing;

10 a respiratory mask system in communication with the housing, the respiratory mask system comprising an air delivery hose and a patient interface including a diffuser;

a flow generator configured to deliver a supply of breathable gas to the patient and being associated with the housing, the flow generator being controllable
15 to supply a controllable source of breathable gas to the patient interface through the air delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period; and

a processor configured to determine a plurality of air flow characteristics of the respiratory mask system at least based on the plurality of flow
20 measurements made during the test period.

18. A CPAP apparatus according to claim 17, wherein the flow sensor is configured to measure at least one air flow through the patient interface during the test period when the flow through the patient interface is open.

19. A CPAP apparatus according to any one of claims 17 and 18, wherein the pressure sensor is configured to measure at least one pressure in the patient interface during the test period when the flow through the patient interface is blocked.

5

20. A CPAP apparatus according to any one of claims 17-19, wherein the processor is configured to determine air flow characteristics of the diffuser using the air flow characteristics of the air delivery hose determined during a first portion of the test period and the pressure measurements made during a second portion of the test period.

10

21. A CPAP apparatus according to any one of claims 17-20, wherein the processor is configured to calculate the air flow characteristics of the air delivery hose as a function of a quadratic expression with two hose constants.

15

22. A CPAP apparatus according to claim 21, wherein the two hose constants comprise:

$$\text{Hose } A = (yX^2 - xY^2) / (xX^2 - Xx^2) \text{ and}$$

$$\text{Hose } B = (xY - yX) / (xX^2 - x^2X),$$

20

wherein x is a lower air flow for the air delivery hose, X is an upper air flow for the air delivery hose, y is a pressure drop in the air delivery hose at the lower air flow and Y is a pressure drop in the air delivery hose at the upper air flow.

23. A CPAP apparatus according to claim 22, wherein the two hose constants (Hose A, Hose B) are used to calculate a true lower test pressure (TrueDiffTP1) and a true upper test pressure (TrueDiffTP2) for the diffuser,

wherein the true lower test pressure is defined as $\text{TrueDiffTP1} = \text{DiffTP1} -$

5 $\text{HoseA} * x - \text{HoseB} * \text{HoseA}(x)^2$, where DiffTP1 is the diffuser flow at a lower pressure for the diffuser, and

wherein the true higher test pressure is defined as $\text{TrueDiffTP2} = \text{DiffTP2} -$
 $\text{HoseA} * X - \text{HoseB} * \text{HoseA}(X)^2$, where DiffTP2 is the diffuser flow at a higher pressure for the diffuser.

10

24. A CPAP apparatus according to any one of claims 17-23, wherein the determining of the air flow characteristics of the mask system is calculated as a function of a quadratic expression with two diffuser constants (Diff A, Diff B).

15 25. A CPAP apparatus according to claim 24, wherein the two diffuser constants comprise:

$$\text{Diff } A = \frac{(zV^2 - vZ^2)}{(vV^2 - v^2V)} \text{ and}$$

$$\text{Diff } B = \frac{(vZ - zV)}{(vV^2 - v^2V)},$$

20 wherein v is a lower pressure for the diffuser, V is an upper pressure for the diffuser, z is a true lower pressure for the diffuser and Z is a true upper pressure for the diffuser.

26. A CPAP apparatus according to any one of claims 17-25, further comprising a flow blocking member configured to block the patient interface, the flow blocking member (50) having a shape that is complementary to a shape of the patient interface.

5

27. A CPAP apparatus according to claim 26, wherein the shape of the flow blocking member is representative of at least one of a human nose and a human face.

10 28. A CPAP apparatus according to claim 26 or 27, wherein the flow blocking member is affixed to the patient interface.

29. A CPAP apparatus according to any one of claims 17-28, wherein the patient interface is configured to allow air to pass therethrough and the diffuser is
15 configured to diffuse exhaled air therethrough during an exhalation phase of a respiratory cycle of the patient.

30. A machine readable medium containing machine executable instructions for carrying out the method according to any one of claims 1-16.

20

31. A CPAP apparatus useful in treatment of a patient, the CPAP apparatus comprising:

a housing;

a respiratory mask system in communication with the housing, the respiratory mask system comprising an air delivery hose and a patient interface including a diffuser orifice;

5 a flow generator configured to deliver a supply of breathable gas to the patient and being associated with the housing, the flow generator being controllable to supply a controllable source of breathable gas to the patient interface through the air delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period;

10 means for determining air flow characteristics of the air delivery hose using flow measurements made during a first portion of the test period when the flow through the patient interface is open;

means for measuring pressure in the patient interface during a second portion of the test period when the flow through the patient interface is blocked; and

15 means for determining air flow characteristics of the orifice using the air flow characteristics of the air delivery hose determined during the first portion of the test period and the pressure measurements made during a second portion of the test period.

32. A CPAP apparatus for use with a respiratory mask system comprising an air delivery hose and a patient interface including a diffuser, the CPAP apparatus
20 comprising:

a housing;

a flow generator configured to deliver a supply of breathable gas to the patient and being associated with the housing, the flow generator being controllable to supply a controllable source of breathable gas to the patient interface through the air

delivery hose during a test period, wherein a plurality of flow measurements of the controllable source of breathable gas are made during the test period; and

a processor configured to determine a plurality of air flow characteristics of the respiratory mask system at least based on the plurality of flow measurements made during the test period.

33. A respiratory mask system for use with a CPAP apparatus of claim 32.

34. A method of calibrating a flow generator in a CPAP apparatus for use with a mask system including a diffuser and an air delivery hose connecting the flow generator and the mask system, the method comprising:

providing the flow generator with two different air flows, representative of a pressure drop in the air delivery hose when flow through the mask system is open;

providing the mask system with two different pressures, representative of a flow of the diffuser and other leaks out of the mask system;

blocking flow through the mask system while providing the mask system with the two different pressures.

35. A method of determining air flow characteristics of a mask system connected to CPAP apparatus comprising a flow generator, the mask system including an air delivery hose and a patient interface including a diffuser, the CPAP apparatus including a controllable air blower, a flow sensor and a pressure sensor, the method comprising:

providing air flow characteristics of the air delivery hose;

measuring pressure in the patient interface when the flow through the patient interface is blocked; and

determining air flow characteristics of the diffuser using the pressure measurements when the patient interface is blocked and the air flow characteristics of the air delivery hose that are provided or determined.

36. A method according to claim 35, wherein the air flow characteristics of the air delivery hose are predetermined.

37. A method according to claim 35, wherein the air flow characteristics of the air delivery hose are measured when flow through the patient interface is open.

38. A CPAP apparatus for performing the method according to any one of claims 1-16 and 34-37.

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

REFER ELECTRONIC DATABASE CONSULTED BELOW.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI & keywords: character, calibrate, coefficient, factor, correlation, parameter, mask, interface, generator, pump, source, blower, pressure, flow, drop, fall, loss, reduction, leak and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/27457 A1 (RESMED LTD) 18 May 2000	

☐ Further documents are listed in the continuation of Box C ☐ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 18 February 2002	Date of mailing of the international search report - 1 MAR 2002
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer Geoff Sadlier Telephone No : (02) 6283 2114